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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,876	09/25/2003	Stephen Donovan	17607 (BOT)	4618

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EXAMINER

KAM, CHIH MIN

ART UNIT PAPER NUMBER

1656

DATE MAILED: 02/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/672,876	DONOVAN, STEPHEN	
	Examiner	Art Unit	
	Chih-Min Kam	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,5 and 13-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4, 5 and 13-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date. _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

1. Claims 1, 4, 5 and 13-21 are pending.

Applicants' amendment and response filed December 2, 2005 is acknowledged.

Applicants' response has been fully considered. Claims 1 and 13 have been amended, claims 2 and 3 have been cancelled, and new claims 14-21 have been added. Therefore, claims 1, 4, 5 and 13-21 are examined.

Withdrawn Claim Rejection- 35 USC § 112

2. The previous rejection of claims 1-2, 4, 5 and 13 under 35 U.S.C. 112, first paragraph is withdrawn in view of applicants' amendment to the claim, applicant's cancellation of the claim, and applicant's response at page 3 of the amendment filed December 2, 2005.

3. The previous rejection of claims 1-5 and 13 under 35 U.S.C. 112, second paragraph, regarding the term "a fermentation medium that is substantially free of an animal derived product" or "an animal derived product", is withdrawn in view of applicants' amendment to the claim, applicant's cancellation of the claim, and applicant's response at pages 4-5 of the amendment filed December 2, 2005.

Withdrawn Claim Rejections-Obviousness Type Double Patenting

4. The previous rejection of claims 1-5 and 13 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9, 16 and 17 of co-pending application 11/072,050, is withdrawn in view of applicant's terminal disclaimer filed December 2, 2005, and applicant's response at page 6 in the amendment filed December 2, 2005.

New Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1, 4, 5 and 13-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claims 1, 4, 5 and 13-21 are indefinite because of the use of the term “a blood derived product” or “an animal derived protein”. The term cited renders the claim indefinite, it is not clear how different is the derived product or derived protein from the parent product in the blood or the parent protein in the animal. The claim is also indefinite as to the animal derived product selected from the group consisting of...., the term “selected from the group consisting of” is a close language indicating a limited number of animal derived products in the group, however, the claim also recites “derived product” or “derived protein”, which is an open language, thus it is not clear whether the group has a limited number of animal derived products or not. The claim is also indefinite as to the claim recites yeast being in the group of vegetable. Claims 4, 5, 14-16 and 18-20 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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7. Claims 1, 14, 15 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Lewis *et al.* (Production of Botulinum Toxin Vol 53, pages 213-230 (1947)).

Lewis *et al.* disclose a culture media containing basal medium having Difco yeast extract 0.5 %, glucose (cerelose) 0.6 %, thioglycolic acid 0.05%, and tap water, adjusted to pH 7.5, and supplements including 0.1% of Peptecase (a tryptic digest of casein) and 2.5% of Gluten (granular product from corn) are used to produce botulinum toxin A having toxicity 10,000 MLD (Table 1, last line; pages 213-216; claims 1, 14, 15 and 17). Although the reference does not specifically indicate the toxin was isolated, the toxicity test indicates the botulinum toxin was produced in the culture medium. Thus, at the time of invention was made, it would have been obvious to one of ordinary skill in the art that botulinum toxin can be obtained from culturing the fermentation medium containing gluten and peptecase (less than 1%), which results in the claimed invention and was, as a whole, prima facie obvious at the time the claimed invention was made.

Conclusion

8. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Patent Examiner



CHIH-MIN KAM
PATENT EXAMINER

CMK

February 09, 2006